K100908

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS JUN 22 2010

Submitter

Company: ..... 3M ESPE AG

Street: ..... ESPE Platz

ZIP-Code, City: ..... D-82229 Seefeld

Federal State: ..... Bavaria

Country: ..... Germany

Establishment Registration Number 9611385

Official Correspondent: ..... Dr. Desi W. Soegiarto,

..... Regulatory Affairs Specialist

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Date: ..... June 09, 2010

Name of Device

Proprietary Name: ..... Unicem HM

Classification Name: ..... Dental cement other than zinc oxide-eugenol

Common Name: ..... Self adhesive cement

Predicate Devices

Unicem Aplicap/Maxicap by 3M ESPE AG, Germany K094007, K020256

Panavia F 2.0 by Kuraray Medical Inc., Japan K032455

Maxcem 2 by Kerr Corporation, U.S.A.,
presumably marketed as Maxcem Elite K073209

Description for the Premarket Notification

Unicem HM is classified as a Dental cement other than zinc oxide-eugenol (21 C.F.R. § 872.3275 [b]) because it is a device composed of various materials other than zinc oxide-eugenol.

Unicem HM in the Clicker™ dispenser is a dual-curing, self-adhesive resin cement for hand mixing. It contains bi-functional (meth)acrylate. The proportion of inorganic fillers is about 70% by weight; the grain size (D 90%) is about 12.5 µm. The mixing ratio, based on volume, is 1 part base paste : 1 part catalyst. The cement is available in various shades.

Unicem HM has been cleared under K062292. This 510(k) Premarket Notification has been submitted in order to seek clearance for additional new Indications for Use listed hereafter:

Final cementation of 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis);
Final cementation of ceramic, composite or metal restorations on implant abutments
Cementation of abutments made of Lava™ zirconium oxide ceramic.

The predicate devices to which Unicem HM has been compared are Unicem Aplicap/Maxicap by 3M ESPE AG, Germany (K094007, K020256), Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Maxcem 2 by Kerr Corporation, U.S.A., presumably marketed as Maxcem Elite (K073209).

As its predicate devices, Unicem HM is a dual-curing (chemical and light) resin based cement system containing methacrylate to be used with metal, composite, and porcelain restorations. Maxcem Elite and Unicem HM are both paste/paste systems.

The intended use of Unicem HM is comparable to the area of the intended use of the predicate devices of Unicem HM.

In this 510(k) premarket notification Unicem HM has been compared to its predicate devices with regard to chemical composition, performance data and indications for use. The comparison for chemistry, performance data and indications for use shows that Unicem HM is substantially equivalent to the predicate devices: Unicem Aplicap/Maxicap by 3M ESPE AG, Germany (K094007, K020256), Panavia F 2.0 by

Kuraray Medical Inc., Japan (K032455) and Maxcem 2 by Kerr Corporation, U.S.A., presumably marketed as Maxcem Elite (K073209).

The following table shows the performance data of Unicem HM and its predicate device Unicem Aplicap:

		Method	Limit	Unicem HM	Unicem Aplicap
Film thickness [µm]		ISO 4049	< 50	9 ± 3	12 ± 2
Working time [sec]		ISO 4049	> 60	pass	pass
Setting time [min:s]		ISO 4049	< 10	03:45	05:00
Radiopacity mm		ISO 4049	> 1.0	2.3	2.4
Flexural strength [MPa]	dark cured	ISO 4049	> 50	57 ± 11	53 ± 7
	light cured	ISO 4049	> 50	87 ± 9	64 ± 6
Compressive strength [MPa]	dark cured	ISO 9917	> 70	247 ± 16	209 ± 15
	light cured	ISO 9917	> 70	281 ± 15	218 ± 13
Surface hardness [MPa]	dark cured	DIN 2039-1	n.a.	202 ± 8	209 ± 13
	light cured	DIN 2039-1	n.a.	280 ± 35	151 ± 10

Biocompatibility testing was carried out.

In summary, it can be concluded that Unicem HM is a safe and effective as as the predicate devices: Unicem Aplicap/Maxicap by 3M ESPE AG, Germany (K094007, K020256), Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Maxcem 2 by Kerr Corporation, U.S.A., presumably marketed as Maxcem Elite (K073209).

Indications for Use

Final cementation of ceramic, composite or metal inlays, onlays, crowns, bridges, 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis);

Final cementation of post and screws;

Final cementation of ceramic, composite or metal restorations on implant abutments;

Cementation of abutments made of Lava™ zirconium oxide ceramic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Desi W. Soegiarto
Regulatory Affairs Specialist
3M ESPE AG Dental Products
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JUN 22 2010

Re: K100908
Trade/Device Name: Unicem HM
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: March 29, 2010
Received: April 1, 2010

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	K100908
Device Name:	Unicem HM
Indications For Use:	Final cementation of ceramic, composite or metal inlays, onlays, crowns, bridges, 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis) Final cementation of post and screws Final cementation of ceramic, composite or metal restorations on implant abutments Cementation of abutments made of Lava™ zirconium oxide ceramic

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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